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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			EXAMINER	
			SORKIN, DAVID L	
		ART UNIT	PAPER NUMBER	
		1723		

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,989	FELT ET AL.	
	Examiner	Art Unit	
	David L. Sorkin	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 November 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 70-76 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-26 and 28-69 is/are rejected.
- 7) Claim(s) 27 is/are objected to.
- 8) Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 & 5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-69, drawn to a centrifugal separator and various subcombinations thereof and combinations therewith, classified in class 494, subclass 60.
 - II. Claim 70-76, drawn to a method of separating a composite fluid, classified in class 494, subclass 37.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus could be used for pumping a single component fluid, such as water, rather than separating a composite fluid. See especially page 20, lines 9-15 of the instant specification. Also, though the process requires "delivering a composite fluid to the composite fluid containment area" composite fluid could be delivered to a different location.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Peter B. Scull on 07 July 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-69. Affirmation of this election must be made by applicant in replying to this Office action. Claims 70-76 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

7. The abstract is objected to because it is too long. 35 CFR 1.72 states "[t]he abstract filed under 35 U.S.C. 111 may not exceed 150 words in length".

Claim Objections

8. In claim 1, line 2, "arts" apparently should read - - parts - -.
9. Applicant is advised that should claim 50 be found allowable, claim 55 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. In claim 9, it is unclear if the phrase "particularly plasma and red blood cells" is a required limitation of the claim, or if the claim is open to other blood components such as white blood cells or platelets.

13. In claim 11, there is lack of antecedent basis for "the respective first and second separated fluid p values, appearing in $p_{1st\ component}^1$ and $p_{2nd\ component}^2$ ". It appears that claim 11 should depend from claim 10, rather than claim 9, to provided proper antecedent basis for the above term.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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15. Claims 1-26, 28-35, 40-57 and 64-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Judson et al. (US 3,489,145). Regarding claim 1, Judson ('145) discloses a centrifuge configuration for centrifugally separating a composite fluid into at least one of the component parts thereof (see abstract), said configuration being adapted to receive a composite fluid from a source and adapted to provide for the delivery of at least one separated fluid component to a separated component receiver (see col. 19 lines 55 to col. 20 line 16) said configuration comprising a separation layer having a fluid receiving area (266 and/or 262 or a portion thereof) which is adapted to be disposed in fluid communication with a composite fluid source (see col. 19, lines 56-60); said separation layer also having a fluid inlet channel (202 and optionally the space between 204 and 196); a circumferential fluid separation channel (274 and/or 208); and at least one separated fluid outlet channel (any, some or all of port 276, port 278 and the four ports 224); wherein the inlet channel is disposed in fluid communication with the receiving area (see Fig. 5; col. 19, lines 56-61); wherein said circumferential separation channel is disposed in fluid communication with said fluid inlet channel (see Fig. 5; col. 19, lines 60-65) and wherein each of said at least one separated fluid outlet channels is also adapted to be disposed in fluid communication with a corresponding component receiver (see col. 17, line 60 to col. 19 line 15). Claim 1 also recites "whereby said fluid inlet and each of said fluid outlet channels also have respective inlet and outlet positions such that said positions are related to each other so as to provide fluid flow control in said separation layer". The inlet and outlet positions of the inlet and outlet channels of Judson ('145) are depicted in Fig. 5. It is considered that in all instances the location of

inlets and outlets (together with other factors) influences the tendency of fluids to flow. Such is merely an acknowledgement of a law of nature, not a further structural limitation of the claimed apparatus. Regarding claim 2, the inlet and outlet positions of the inlet and outlet channels of Judson ('145) are depicted in Fig. 5. It is considered that these channels are capable of providing the fluid imbalance stipulated in claim 2. It is noted that the inlet channel 202 is coincident with the axis of rotation while the outlet channel(s) is/are spaced away from the axis of rotation; therefore, neglecting density differences of the fluids in the respective channels, the fluid pressure balance would be in favor of flow from the inlet of the inlet channel to the outlet(s) of the outlet channels. However, as explained throughout the instant specification, for example on page 18 line 23 to page 19 line 17, the condition for balance depends upon the densities of the fluid and components thereof. As held in *Ex parte Thibault*, supra., "[e]xpressions relating the apparatus to contents thereof are of no significance in determining patentability of the apparatus claim". In summary, it is considered that although the system of Judson ('145) would be capable of creating the fluid pressure imbalance recited in claim 2, whether an actual fluid pressure imbalance occurs is a matter of how the claimed device is used. As held in *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), "recitation with respect to the manner in which the claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus". Likewise, claims 3-21 are considered not to further structurally limit the claimed apparatus, because the "heights" or "lengths" referred to in these claims are dependent upon the density of fluids intended to be used with the apparatus. Claims 3-8, 10, 12-

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15, 17, 19 and 20 make no attempt to specify these densities. Claims 9, 11, 16, 18 and 21 do mention whole blood and specific blood components, which are recognized as having at least approximately defined densities; however, these claims still do not imply structural limitations, because the claims are not limited to one particular component for a given channel. Instead, the claims are open to varying amounts of multiple components in each channel, for example with interfaces of unspecified position between the multiple components (see for example claim 18). Regarding claim 22, the configuration includes at least an outlet layer (254) which is disposed in fluid communication with said at least one outlet channel (see Fig. 5; col. 19 line 66 to col. 20 line 16). Regarding claims 23 and 24, the outlet layer is depicted in Fig. 5 and being above the separation layer; however, it is considered that it may be above or below the separation layer depending upon the overall orientation of the entire apparatus in a particular use, and hence "above" and "below" are not structurally distinct limitations when recited in separate claims. Regarding claim 25, the at least one outlet channel includes a first and second outlet channel and each of said first and second outlet channel are disposed in discrete fluid communication with the outlet layer from the separation layer (see Fig. 5; col. 19 line 66 to col. 20 line 16). Regarding claim 26, the outlet layer is a first outlet layer (254) and the configuration includes a second outlet layer (256); and the at least one outlet channel includes first and second outlet channels; whereby the first outlet channel is disposed in fluid communication with said first outlet layer and said second outlet channel is disposed in communication with said second outlet layer (see Fig. 5; col. 19 line 66 to col. 20 line 16). Regarding claims 28 and 29,

the outlet layers (254,256) are both depicted in Fig. 5 and being above the separation layer; however, it is considered that the outlet layers may be above or below the separation layer depending upon the overall orientation of the entire apparatus in a particular use, and hence "above" and "below" are not structurally distinct limitations when recited in separate claims. Regarding claim 30, the outlet layer is disposed in fluid communication with at least one out conduit member (see col. 19, lines 11-15), which is adapted to be disposed in fluid communication with a storage container (such as 116, 118). Regarding claim 31, the at least one outlet channel includes first and second outlet channels and each said first and second outlet channels is disposed in discrete fluid communication with the outlet layer; and wherein said at least one outlet conduit member includes first and second outlet conduit members each of which being in discrete fluid communication with the respective first and second outlet channels (see Fig. 5; col. 19 lines 4-15; col. 19 line 65 to col. 20 line 16), and adapted to be disposed in fluid communication with respective first and second storage containers (such as 116, 118). Regarding claim 32, said at least one separated fluid channel is also adapted to be disposed in fluid communication with a corresponding fluid receiver (such as 116 or 118). Claims 33 and 34 do not require any specific further structural limitations, but instead discussed how fluid is delivered in an intended operation. It is considered that the configuration of Judson ('145) is capable of delivering fluid to the outlet channels with retained kinetic energy because the inlet is coincident with the axis of rotation and the outlets are all radially outward from the axis. In analogy with gravity, the outlets are "downhill" from the inlet. Because the outlets are at lower potential energy ("down

hill") the fluid will be pumped and the high potential energy of the fluid in the inlet will be transferred to kinetic energy to maintain an energy balance. Regarding claim 35, the examiner first notes that the "separated component receiver" discussed in the claim is not positively recited as part of the claimed apparatus. Claim 35 does not require any specific further structural limitations, but instead discusses how fluid is delivered in an intended operation. It is considered that in the configuration of Judson ('145) separated fluid is capable of being delivered by gravity drainage, for example a receiver is placed at an elevation that is below the outlets. Regarding claim 40, Judson ('145) discloses four channels each referred to as "224". One of these four channels may be considered a "balance channel". These channels (224) are disposed in communication with the circumferential channel (see Fig. 5). Regarding claim 41, said balance channel is disposed in fluid communication with an outlet layer (254). Regarding claim 42, said balance channel is an outlet channel (224), which provides for flow of a separated component fluid therethrough (see col. col. 17, lines 71-73). Regarding claim 43, said circumferential channel is of a first width (in portion 208) adjacent the inlet channel and is of a second wider width (in portion 274) adjacent the balance channel (see col. 17, lines 24 and 25). Regarding claim 44, said circumferential channel is of a first width (in portion 208) adjacent the inlet channel and is of a second wider width (in portion 274; see col. 17, lines 24 and 25). The two widths are present around the entire circumference, including at diametrically opposed portions, for example at the left and right edges in Fig. 5. Regarding claim 45, the at least one outlet channel includes first (224) and second (276) outlet channels and the configuration further includes an

interface wall (including surfaces 242, 244) disposed in the circumferential channel between said first and second outlet channels (see Fig. 5). Regarding claim 46, the configuration is comprised within a rotor (see col. 15, lines 26-40, Fig. 5). Regarding claim 47, the rotor is comprised within a housing (162) said rotor and housing being a centrifuge unit (52). Regarding claim 48, the rotor is comprised within a housing (162) said rotor and housing being a centrifuge unit (52). It is considered that the housing and rotor are capable of being disposed of, if one chooses to do so. As held in *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), "recitation with respect to the manner in which the claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus". It is noted for the record; however, that Judson ('145) explicitly discusses disposing of the centrifuge bowl in col. 8, lines 60-66. Regarding claim 49, the rotor is comprised within a housing (162) said rotor and housing being a centrifuge unit (52); whereby said centrifuge unit has connected thereto at least one tubing line (see col. 19, lines 1-15 and col. 19 line 65 to col. 20 line 16). Regarding claim 50, said centrifuge unit has connected thereto at least one inlet tubing line (see col. 19, lines 1-15 and 48-60). Regarding claim 51, said centrifuge unit has connected thereto at least one outlet tubing line (see col. 19, lines 4-15 and col. 19 line 65 to col. 20 line 16). Regarding claim 52, said outlet tubing line has connected thereto at least one container (116 and/or 118). Regarding claim 53, said centrifuge has connected thereto at least first and second outlet tube lines (see col. 19, lines 4-15 and col. 19 line 65 to col. 20 line 16). Regarding claim 54, each of said first and second tubing lines has connected thereto respective first and second storage containers (116,

118). Regarding claim 55, said centrifuge unit has connected thereto at least one inlet tubing line (see col. 19, lines 1-15 and 48-60). Regarding claim 56, said inlet tubing line has connected thereto at least one access device (64). Regarding claim 57, Judson ('145) discloses a centrifugal separation system for use in a fluid separation system to centrifugally separate a composite fluid into composite components thereof, said centrifugal separation device comprising: a centrifugal drive motor base (166,168,170,156); a centrifugal rotor housing (162,152,256) which is adapted to be disposed in an operable rotor-driving position on said centrifugal drive motor base, said housing having a fluid inlet port (356) and at least one fluid outlet port (358,360,362); and a rotor (178,200,226,254) disposed in a freely rotatable position within said housing, said rotor having a fluid receiving area (322, 266) which is disposed in fluid communication with the fluid inlet port of said rotor housing; said rotor also having a fluid inlet channel (202, 262 and optionally the space between 204 and 196), circumferential fluid separation channel (274 and/or 208) and first and second separated fluid outlet channels (any two of port 276, port 278 and the four ports 224); wherein said inlet channel is disposed in fluid communication with said fluid receiving area (see Fig. 5; col. 19, lines 57-62) and wherein said circumferential separation channel is disposed in fluid communication with said fluid inlet channel and said first and second outlet channels (see Fig. 5; col. 19 line 61 to col. 20 line 16); at least one of said first and second separated fluid outlet channels also being disposed in fluid communication with said at least one fluid outlet port of said housing (for example 276 is in communication with 358, 278 is in communication with 360 and each of the four ports

224 is in communication with 162; see Fig. 5, col. 19 line 61 to col. 20 line 16).

Regarding the final limitation of claim 57, "said first and second fluid outlet channels also having respective first and second lengths wherein said lengths are related to each other so as to provide a substantial hydraulic balance for respective fluids flowing therethrough", while it is generally considered the condition of balance will depend on the density of the fluid flowing through the channels and the liquid level in the channels, and is hence an aspect of use rather than structure, in Judson ('145) four identical outlet channels 224, each intended to carry plasma, are disclosed. It is considered that these channels, being identical, have lengths that would provide a substantial fluid balance for the respective plasma flows therethrough. Regarding claim 64, Judson ('145) discloses a rotor (178,200,226), tubing (see col. 19, lines 11-15) and container (64,116,118) system for use in the separation of a composite fluid into separated components, the system comprising a centrifuge unit (52) having a housing (162) and a rotor (178,200,226) disposed in freely rotatable disposition within the housing (see col. 15, lines 26-40; Fig 5); a first separated component container (116) and a tubing line (see col. 19, lines 11-15) whereby the first separated component container is connected to said centrifuge unit by the tubing line (see Fig. 1). It is considered that the centrifuge unit is capable of being disposed of, if one chooses to do so. As held in *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), "recitation with respect to the manner in which the claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus". It is noted for the record; however, that Judson ('145) explicitly discusses disposing of the centrifuge bowl in col. 8, lines

60-66. Regarding claim 65, the centrifuge unit is connected to an access line (including 90), which may be used to connect to a donor/patient (50) (see Fig. 1). Regarding claim 66, the system further comprised a second separated component container (118); and said second separated component container is connected to said centrifuge unit by a second tubing line (see col. 19, lines 11-15; Fig. 1). Regarding claim 67, Judson ('145) discloses the rotor being construct of "polycarbonate". Rosemeier et al. (US 4,342,420), col. 4, lines 10-13, is cited as evidence that polycarbonate is a rigid material. Regarding claims 68 and 69, Judson ('145) discusses the rotor being plastic in col. 16, line 17. Regarding the process by which the rotor is intend to be made, such as blow molding or injection molding, "The patentability of a product does not depend on its method of production", *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

16. Claims 1-21, 36-39 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Burd et al. (US 5,186,844). Regarding claim 1, Burd ('844) discloses a centrifuge configuration for centrifugally separating a composite fluid into at least one of the component parts thereof (see abstract), said configuration being adapted to receive a composite fluid from a source and adapted to provide for the delivery of at least one separated fluid component to a separated component receiver (34) said configuration comprising a separation layer having a fluid receiving area (17,17') which is adapted to be disposed in fluid communication with a composite fluid source; said separation layer also having a fluid inlet channel (22); a circumferential fluid separation channel (22); and at least one separated fluid outlet channel (20); wherein the inlet channel is disposed in fluid communication with the receiving area (see Fig. 2, col. 6, lines 56-60); wherein

said circumferential separation channel is disposed in fluid communication with said fluid inlet channel (see Fig. 2, col. 6, lines 56-60) and wherein each of said at least one separated fluid outlet channels is also adapted to be disposed in fluid communication with a corresponding component receiver (34). Claim 1 also recites "whereby said fluid inlet and each of said fluid outlet channels also have respective inlet and outlet positions such that said positions are related to each other so as to provide fluid flow control in said separation layer". The inlet and outlet positions of the inlet and outlet channels of Burd ('844) are depicted in Fig. 2. It is considered that in all instances the location of inlets and outlets (together with other factors) influences the tendency of fluids to flow. Such is merely an acknowledgement of a law of nature, not a further structural limitation of the claimed apparatus. Regarding claim 2, the inlet and outlet positions of the inlet and outlet channels of Burd ('844) are depicted in Fig. 2. It is considered that these channels are capable of providing the fluid imbalance stipulated in claim 2. It is noted that the inlet of inlet channel 22 is more radially inward than the outlet of the outlet channel 32; therefore, neglecting density differences of the fluids in the respective channels, the fluid pressure balance would be in favor of flow from the inlet of the inlet channel to the outlet of the outlet channel. However, as explained throughout the instant specification, for example on page 18 line 23 to page 19 line 17, the condition for balance depends upon the densities of the fluid and components thereof. As held in *Ex parte Thibault*, supra., "[e]xpressions relating the apparatus to contents thereof are of no significance in determining patentability of the apparatus claim". In summary, it is considered that although the configuration of Burd ('844) would be capable of creating

the fluid pressure imbalance recited in claim 2, whether an actual fluid pressure imbalance occurs is a matter of how the claimed device is used. As held in *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), "recitation with respect to the manner in which the claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus". Likewise, claims 3-21 are considered not to further structurally limit the claimed apparatus, because the "heights" or "lengths" referred to in these claims are dependent upon the density of fluids intended to be used with the apparatus. Claims 3-8, 10, 12-15, 17, 19 and 20 make no attempt to specify these densities. Claims 9, 11, 16, 18 and 21 do mention whole blood and specific blood components, which are recognized as having at least approximately defined densities; however, these claims still do not imply structural limitations, because the claims are not limited to one particular component for a given channel. Instead, the claims are open to varying amounts of multiple components in each channel, for example with interfaces of unspecified position between the multiple components (see for example claim 18).
Regarding claim 36, the configuration further includes a second inlet channel (22'), a second circumferential channel (20') and at least one outlet channel (32'); whereby said second inlet channel is disposed in fluid communication with said fluid receiving area (see Fig. 2; col. 6, lines 56-66); wherein said second circumferential channel is disposed in fluid communication with said second fluid inlet channel and with the second separated fluid outlet channel (see Fig. 2); and wherein said at least one separated fluid outlet channels is also adapted to be disposed in fluid communication with a corresponding separated component receiver (34'). Claim 36 also recites "whereby

said second fluid inlet and each of said second at least one fluid outlet channels also have respective lengths such that said lengths are related to each other so as to provide fluid flow control in said separation layer". As discussed with regard to claim 1 above, such a statement is merely an acknowledgement of a law of nature, not a further structural limitation of the claimed apparatus. Regarding claim 37, the receiving areas (17,17') of said configuration further includes a septum (the material between 17 and 17') which divides said receiving area into first (17) and second (17') parts, said first part being in communication with the first inlet channel and the second part in communication with the second inlet channel. Regarding claim 38, the second inlet channel, the second circumferential channel and the second outlet channel are disposed in said configuration so as to provide a weight balance to said configuration relative to said first inlet channel and the first circumferential channel and the first outlet channel (see symmetry of Fig. 2; col. 2, lines 2-6). Regarding claim 39, the second inlet channel; the second circumferential channel and the second outlet channel are disposed diametrically opposite said first inlet channel; the first circumferential channel and the first outlet channel (see Fig. 2). Regarding claim 46, the configuration is comprised within a rotor (10).

17. Claim 60 is rejected under 35 U.S.C. 102(a) as being anticipated by WO 00/44502. WO 00/44502 discloses a separation device comprising a rotor (5) having an axial, a radial and a circumferential orientation, wherein said rotor has a circumference and is rotatable about said axial orientation (see Fig. 1 where "R" designates the axis of rotation); a housing (1) in which the rotor is disposed; whereby said housing has an inlet

opening (9) and at least one outlet opening (22/23); said inlet opening being disposed substantially perpendicular to the plane of rotation of said rotor (see Fig. 1 where inlet opening 9 is as shown coincident with the axis of rotation "R"); said outlet opening being disposed substantially tangential to said circumference of said rotor (see page 4, lines 24-27; Fig. 2).

18. Claims 61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by IBM Technical Disclosure Bulletin, vol. 17, issue 2, pages 404-405 ("IBM" herein). (Pages renumbered 1-3 on reprinted database copy provided with this office action). Regarding claim 34, IBM discloses a composite fluid separation device comprising a rotor having an axial, radial and a circumferential orientation; wherein said rotor has a circumference an is rotatable about said axial orientation (see Figs. 1 and 2; pages 1 and 2); said rotor having a substantially centrally disposed containment pocket (the region between the intermost two opposed semicircles, near the center of Fig. 2), an inlet channel (where the words "WHOLE BLOOD" appear in Fig. 2) communicating with said containment pocket; a peripheral channel communicating with said inlet channel (see sentence bridging pages 1 and 2 and see Fig. 2); an outlet channel (where an arrow and the word "PLASMA" appear in Fig. 2) communicating with said peripheral channel, whereby the outlet channel is adapted to be connected in fluid communication with a collection container (as seen in Fig. 2, the outlet channel is connected in fluid communication the collection container designated by the words "PLASMA COLLECT VOLUME"); whereby said inlet channel has a respective height h_c and the outlet channel has a respective height h_1 and h_c is greater than h_1 (see Fig. 2). Note that according to the

instant specification "height" is the distance radially inward toward an axis of rotation, from an arbitrary circle with the axis at its center (see page 17 line 29 to page 18 line 9 of the instant specification). The "WHOLE BLOOD" channel of the reference is of greater "height" because it terminates more radially inwardly than the "PLASMA" channel. Regarding claim 35, the rotor further comprises a second outlet channel (the other of the twin "PLASMA" channels); and a second collection pocket (the other of the twin "PLASMA COLLECT VOLUME" pockets) communicating with said second outlet channel; whereby h_c is greater than h_1 or h_2 (see Fig. 2). Regarding claim 36, , the rotor further comprises a second outlet channel (the other of the twin "PLASMA" channels); and a second collection pocket (the other of the twin "PLASMA COLLECT VOLUME" pockets) communicating with said second outlet channel; whereby the heights of the identical channels outlet channels are identical (see Fig. 2).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claim 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Judson ('145) in view of Ontko et al. (US 3,304,990). Judson ('145) was discussed above with regard to claim 57. Regarding claim 58, Judson ('145) fails to disclose the rotor containing magnetically reactive material and being rotated by a rotating magnetic field in the motor base. Ontko ('990) teaches a centrifugal drive motor base (15,47,40) and a rotor housing (11) (in which a rotor 27 freely rotates) positioned on the base wherein the base produces a rotating magnetic field (see col. 3, lines 39-41) and a rotor having a magnetically reactive material which is adapted to rotate with the rotating magnetic field produced by said motor base, whereby said rotor is caused to rotate by the co-action of said magnetically reactive material and said rotating magnetic field (see col. 3 line 5 to col. 4 line 25). It is considered that it would have been obvious to one of ordinary skill in the art to have provided the system of Judson ('145) with the magnetically reactive rotor material and rotating magnetic field drive base of Ontko ('990) because Ontko ('990) explains that such a magnetic drive provides the advantage of allowing the centrifuge to be explosion proof by isolating the housing from the motor (see col. 1, lines 45-56 and col. 3, lines 72-75). Regarding claim 59, the motor base of Ontko ('990) has a flat top surface (15); and the rotor housing has a flat bottom surface, whereby the flat top surface and the flat bottom surface co-act to provide the adaptation of the rotor housing to be disposed in operable position on said motor base (see Fig. 1).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 61-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-36 of copending Application No. 10/005,341. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Regarding claim 61, claim 34 of 10/005,341 is considered to require all the limitations of instant claim 61. The only difference between the claims is that claim 34 of 10/005,341 positively recites "a collection pocket communicating with said outlet channel" while instant claim 61 recites "whereby the outlet channel is adapted to be connected in fluid communication with a collection container". However, it is considered that the positive recitation in claim 34 of "a collection pocket communicating with said outlet channel" satisfies the "...adapted to be connected in fluid communication..." limitation of instant claim 61. Likewise, claim 35 of 10/005,341 is considered to require all the limitations of instant claim 62, the only difference being the positive recitation of collection pockets in

claim 35, versus the "adapted to" language of instant claim 62. Likewise, claim 36 of 10/005,341 is considered to require all the limitations of instant claim 63, the only difference being the positive recitation of collection pockets in claim 36, versus the "adapted to" language of instant claim 63.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

24. Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The closest prior art is Judson et al. (US 3,489,145). Judson ('145) fails to disclose the claimed orientation of the two outlet layers relative to the separation layer, one outlet layer being above and the other below the separation layer.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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872-9310 for regular communications and 703-872-9311 for After Final
communications.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is 703-308-
0661.



David Sorkin

July 14, 2003
